NOV 0 6 2001

K011899 p.1/3

510(k) Summary as required by section 807.92(c)

6.1 Submitter's Name & Address:

Perimed AB
Datavägen 9A
SE-175 26 Järfälla, Sweden
Tel: (011) 46 8 580 119 90
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Official Correspondent: Björn Bakken
Contact Person for this submission: Björn Bakken

6.2 Trade Name:

Device name: PF 5050 Pressure Unit

Common name, Classification number, Class & Regulation Number:

Common Name	*Classification Number*	*Class*	*Regulation Number*
Air Plethysmograph/Pulse Volume Recorder	(Unknown)	II	870.2100

6.3 Predicate Device Identification:

Legally marketed devices to which equivalence is being claimed	*510(k) #*
MODEL PV2000 VASCULAR MICROLABORATORY, VASAMEDICS	K951486

6.4 Device Description (for detailed description see Section 12.4):

The PF 5050 Pressure Unit is a modular unit that can be installed in the PeriFlux System 5000. The device provides Pulse Volume waveform Recordings (PVR) on various limb and digit extremities made possible through air plethysmography. The PF 5050 Pressure Unit includes a small display where the mean cuff pressure is displayed.

The PVR tracing is accomplished by attaching a standard blood pressure cuff on various areas of the extremities. To provide skin contact, atmospheric air is inflated to approximately 50 – 65 mmHg using the balloon pump supplied with a standard blood pressure gauge. A pressure transducer records the pressure

K011899 p.2/3

change in the cuff (Pulse Volume waveforms) secondary to change in volume of the extremity segment under the cuff during repeated cardiac cycles.

The PeriFlux System 5000 is a multi-channel, multi-functional system capable of hosting one, two, three or four function units including for example a PF 5010 LDPM Unit for blood perfusion measurements. The PeriFlux 5001 Main Unit accommodates up to four different function units of the same type or of different types enabling simultaneous measurements of several parameters. There are three different function unit types available at the moment.

PF 5010 LDPM Unit for blood perfusion measurements.
PF 5020 Temp Unit for temperature measurements.
PF 5040 tcpO2 / pCO2 for measurements of transcutaneous O2 and CO2.

The PeriFlux System 5000 with the Modular laser Doppler system for blood perfusion measurement was cleared for marketing under 510(k) application K974285 on May 28, 1998.

6.5 Intended Use of the Device:

The PF 5050 Pressure Unit is intended for Pulse Volume waveform Recordings (PVR) on limbs and digits.
It is also intended to measure the mean pressure in a blood pressure cuff to simplify simultaneous measurements of perfusion and pressure when used in conjunction with a laser Doppler perfusion monitor. This simplifies some typical laser Doppler measurements that include occlusions with blood pressure cuffs, such as: digital systolic blood pressure, Post Occlusive Reactive Hyperemia (PORH) and Skin Perfusion Pressure (SPP).

6.6 Summary of technological characteristics of Device and Predicate Device:

The PF 5050 Pressure Unit is substantially equivalent to the following predicate device:

Manufacturer	*Legally marketed devices to which equivalence is being claimed*	*510(k) #*
VASAMEDICS	MODEL PV2000 VASCULAR MICROLABORATORY	K951486

This conclusion is based on the following:

Indications for use:

K011899 p. 3/3

When installed in the PeriFlux System 5000, the PF 5050 Pressure Unit is intended to monitor Pulse Volume waveform Recordings (PVR).
When used together with PF 5010 LDPM Unit (laser Doppler unit) it is also possible to record Skin Perfusion Pressure.

Technological Comparison:

The Vasamedics MODEL PV2000 VASCULAR MICROLABORATORY has the same indications for use as the PF 5050 Pressure Unit in that they both are measuring Pulse Volume Waveform Recordings (PVR).
When the PeriFlux System 5000 also includes a PF5010 laser Doppler perfusion monitor it is possible in both instruments to measure Skin Perfusion Pressure. The instruments provide similar types of tracings and have comparable output ranges. Both instruments can be connected to external devices for data analysis

A more detailed comparison of the design and performance features of these devices is provided in appendix B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2001

Mr. Björn Bakken
Vice President
Quality Assurance & Regulatory Affairs
Perimed AB
Datavägen 9A
SE-175 26 Järfälla, Sweden

Re: K011899
Trade Name: Perimed PF 5050 Pressure Unit
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: October 8, 2001
Received: October 12, 2001

Dear Mr. Bakken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 6 2001

510(k) Number (if known): K011899

Device Name: PF 5050 Pressure Unit

Indications For Use: Use of the PF 5050 Pressure Unit is indicated for non-invasive Pulse Volume waveform Recordings (PVR) on extremities of patients with vascular diseases.

It is also intended to measure and control the pressure in a blood pressure cuff to simplify simultaneous measurements of perfusion and pressure when used in conjunction with a laser Doppler perfusion monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011899